UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

APR 17 2013

MEMORANDUM

SUBJECT: Environmental risk assessment for the FIFRA Section 3 registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (PC Code: 006401; EPA File Symbol 6218-IG); Decision No. 458629; Submission No. 924489; DP Barcode No. 410961

FROM: Shannon Borges, Biologist
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division, 7511P

TO: Denise Greenway, Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division, 7511P

I. Ecological Risk Assessment

A. Introduction

Summit Chemical Company (hereafter "Summit") has applied for FIFRA Section 3 registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (hereafter "*Bti* SUM-6218") in a manufacturing use product (Summit® Bti MP, EPA File Symbol 6218-IG). The manufacturing use product is 100% active ingredient (a.i., consisting of Bti SUM-6218 solids, spores, and delta-endotoxin). *Bti* SUM-6218 is a new a.i., and thus requires a review to assess the potential risks to nontarget organisms. This memorandum contains BPPD's ecological risk assessment for this new a.i. and its proposed uses.

B. Summary of Nontarget Effects Data

Table 1 provides the status of the data requirements for the active ingredient *Bti* SUM-6218. One guideline study and scientific rationales were submitted to satisfy nontarget organism data requirements as published in 40 CFR § 158.2150. Summit claims that *Bti* SUM-6218 is identical to the bacterium originally isolated in Israel in 1977, which is the active ingredient in other registered *Bti* based pesticides. This claim was confirmed[1], which allows for bridging to studies currently available in EPA's database of nontarget studies on *Bti*. Data Evaluation Records

[1] See memoranda from I. Barsoum to D. Greenway dated July 10, 2012 (with accompanying Data Evaluation Record) and November, 13, 2012.

(DERs) for the guideline study and the rationales are attached to this memorandum, and the data are discussed in Section C below. The information provided is sufficient to satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for this new a.i. and its proposed manufacturing use. Additional testing at higher tiers is not required.

Table 1. Summary of data submitted to comply with requirements published in 40 CFR § 158.2150 to support the registration of *B. thuringiensis* subsp. *israelensis* strain SUM-6218.

Data Requirement	OPPTS Guideline	Results Summary and Classification	MRID No.
Avian oral toxicity/pathogenicity	885.4050	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842702, 41439006, and 41842703 **Classification: Acceptable**	48682620
Avian inhalation toxicity/pathogenicity	885.4100	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842702, 41439006, and 41842703 **Classification: Acceptable**	48682621
Wild mammal toxicity/pathogenicity	885.4150	Rationale and studies cited are sufficient to satisfy the data requirement. Cited Accession Nos./MRIDs: 142733, 41046704, 42006502, 43186101, 40951102, 96520, 96527, 96533, 109492, and 246968 **Classification: Acceptable**	48682622
Freshwater fish toxicity/pathogenicity	885.4200	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41439008, 41980105, 41439007, and 41842704 **Classification: Acceptable**	48682623
Freshwater invertebrate toxicity/pathogenicity	885.4240	A 21-day study shows that the EC_{50} to *Daphnia magna* based on mortality/immobility is > 1.0×10^3 CFU/mL, the NOEC based on reproduction was 1.0×10^6 CFU/mL, and the NOEC based on body weight was 1.0×10^3 CFU/mL (though, effect was weight gain not loss). Study is sufficient to show that heat labile exotoxins are not produced. **Classification: Acceptable**	48682624
Estuarine/marine fish and invertebrate testing	885.4280	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41540402, 41842706, 41540401, 41842707, and 41439010 **Classification: Acceptable**	48682625
Nontarget plant testing	885.4300	Rationale submitted was sufficient to determine that adverse effects are not expected in plants as a result of exposure to *Bti* SUM-6218. **Classification: Acceptable**	48682626
Nontarget insect testing	885.4340	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842708, 41842709, 41842710, and 41842711 **Classification: Acceptable**	48682627
Honey bee testing	885.4380	Rationale and studies cited are sufficient to satisfy the data requirement. Cited MRID: 41842711 **Classification: Acceptable**	48682628

Data Requirement	OPPTS Guideline	Results Summary and Classification	MRID No.
Endangered Species Assessment	Non-guideline	A summary of information was provided. These data are not required. **Classification: Supplemental**	48682629

C. Ecological Exposure and Risk Characterization

Since the proposed registration is for a manufacturing use product only, exposure to nontarget organisms is not anticipated. Additional consideration for nontarget exposure and a risk assessment will be necessary if an end use product containing *Bti* SUM-6218 is proposed for registration.

In the 1998 *Bacillus thuringiensis* Reregistration Eligibility Decision (RED)[2], EPA concluded that risks to nontarget organisms exposed to *Bacillus thuringiensis* (including *Bti*) are unlikely as long as the presence of heat labile exotoxins or beta-exotoxins is minimized. In addition to information submitted to show that beta-exotoxins will not be produced (see reference in footnote 1), Summit provided EPA with an acceptable 21-day study on *Daphnia* (MRID 48682624, with supplemental information in MRIDs 48954200 and 48954201) to show that *Bti* SUM-6218 does not produce heat-labile exotoxins. This study is summarized below and more fully described in the attached DER, and provides a satisfactory basis to make similar conclusions about *Bti* SUM-6218 that have been made for other *Bti* based pesticides.

Bti SUM-6218 also has been shown to be identical to the *Bti* originally isolated and registered with EPA. Therefore, bridging to previously submitted data and extending conclusions on nontarget organisms from the RED to the current proposed registration of *Bti* are both possible. This was Summit's approach to addressing the data requirements. In addition to citing EPA's conclusions, specific data and other information were cited to show that adverse effects on nontarget organisms are not expected as a result of the proposed registration of *Bti* SUM-6218. The data and other rationale submitted to support the nontarget risk assessment are described below.

Avian Oral and Inhalation Toxicity/Pathogenicity

Results of previously submitted studies show that *Bti* was practically nontoxic to birds at 3.1 g/kg/day and 5 ml/kg/day to Northern bobwhite (*Colinus virginianus*) and mallard (*Anas platyrhynchos*) in avian oral studies (MRIDs 41842702, 41439006, and 41842703). Summit also cited toxicity data for mammals; however, EPA does not support citation of mammalian toxicity/pathogenicity data to fulfill avian data requirements, and these citations were not considered. Based on the available information, adverse effects to birds are not expected from exposure to *Bti* SUM-6218.

Wild Mammal Toxicity/Pathogenicity

[2] USEPA. 1998. Reregistration Eligibility Decision (RED) *Bacillus thuringiensis*. EPA 738-R-98-004. Available at http://www.epa.gov/oppsrrd1/REDs/0247.pdf

Mammalian toxicity/pathogenicity data submitted previously to support registrations of *Bti*, including Accession Nos./MRIDs 142733, 41046704, 42006502, 43186101, 40951102, 96520, 96527, 96533, 109492, and 246968. Details of the findings of these studies are presented in the 1998 *Bt* RED. EPA also concluded in the RED that no known mammalian health effects have been demonstrated in any infectivity/pathogenicity study with *Bacillus thuringiensis*. Additionally, Summit submitted an Acute Injection Toxicity/Pathogenicity study and additional rationale to satisfy toxicology data requirements to support the human health risk assessment (see footnote 1 for references), and EPA has no reason to believe that studies with laboratory animals would not be representative of potential effects on wild mammals. Therefore, based on the rationale, studies cited, and the study submitted, adverse effects to wild mammals are not expected as a result of exposure to *Bti* SUM-6218.

Freshwater Fish Toxicity/Pathogenicity

In addition to rationale citing previous conclusions on the currently registered *Bti*, Summit cited previously submitted data. Under Guideline 885.4200, Freshwater Fish Toxicity, *Bti* was found to have an aqueous $LC_{50} > 8.7 \times 10^9$ cfu/L; oral $LC_{50} > 1.7 \times 10^{10}$ cfu/g food and an aqueous $LC_{50} > 1.4 \times 10^{10}$ cfu/L; oral $LC_{50} > 5.3 \times 10^9$ cfu/g food in rainbow trout and an aqueous $LC_{50} > 8.9 \times 10^9$ cfu/L; oral $LC_{50} > 1.3 \times 10^{10}$ cfu/g food and aqueous $LC_{50} > 1.6 \times 10^{10}$ cfu/L; oral $LC_{50} > 4.3 \times 10^9$ cfu/g food in bluegill sunfish (MRIDs 41439008, 41980105, 41439007, 41842704). This information is sufficient to conclude that adverse effects to freshwater fish resulting from exposure to *Bti* SUM-6218 are unlikely.

Freshwater Invertebrate Toxicity/Pathogenicity

A 21-day study with *Daphnia magna* (MRID 48682624) was submitted to demonstrate the effects of Bti SUM-6218 on freshwater invertebrates. The LC_{50} could not be calculated; however, it was determined to be $> 1.0 \times 10^3$ CFU/mL. It is noted also that no effects on survival were observed at the two highest concentrations tested (1.0×10^5 and 1.0×10^6 CFU/mL). The NOEC and LOEC based on reproduction are 1.0×10^6 and $> 1.0 \times 10^6$ CFU/mL, respectively. The NOEC and LOEC based on mass of surviving adults is 1.0×10^3 and 1.0×10^4 CFU/mL, respectively; however, it is noted that in this case the effect was an increase in body weight, which is not considered deleterious in this case. The study is sufficient to demonstrate that *Bti* SUM-6218 does not cause detrimental effects to freshwater invertebrates and also does not product heat labile exotoxins.

Estuarine/Marine Fish and Invertebrate Testing

In addition to rationale citing previous conclusions on the currently registered *Bti*, Summit cited previously submitted data. Under Guideline Number 885.4280, *B. thuringiensis* subsp. *israelensis* was found to have a NOEL $> 2.0 \times 10^{10}$ cfu/g, NOEL $> 4.2 \times 10^9$ cfu/g food for grass shrimp; a NOEL$> 2.0 \times 10^{10}$ cfu/g food, oral LC $> 2 \times 10^{10}$ cfu/g food, $LC_{50} > 7.2 \times 10^9$ for sheepshead minnow; and a NOEL = 50 mg/kg sediment with a marine copepod (MRIDs 41540402, 41842706, 41540401, 41842707, and 41439010). This information is sufficient to

conclude that adverse effects to estuarine/marine fish and invertebrates resulting from exposure to *Bti* SUM-6218 are unlikely.

Nontarget Plant Testing

EPA requires nontarget plant testing only when the active ingredient is taxonomically related to known plant pathogens. *Bti* is not a plant pathogen and is not related to known plant pathogens, so testing on nontarget plants is not required. Adverse effects to nontarget plants as a result of exposure to *Bti* SUM-6218 are not anticipated.

Nontarget Insect and Honey Bee Testing

Summit provided rationale as well as data citations to fulfill these data requirements. Summit referenced EPA's conclusions for nontarget insects and honey bees in the 1998 RED, and noted that insect testing was not required (except for honey bee) because *Bt* functions by a toxic mode of action and does not cause epizootics in the field. Additionally, they cite previously submitted data on *Bti*. Under Guideline 885.4340, *B. thuringiensis* subsp. *israelensis* was found to have a 16-day $LC_{50} > 1.5 \times 10$ and 16-day NOEL = 2.5×10^4 cfu/g for the green lacewing; 30-day $LC_{50} > 7.9 \times 10^7$ cfu/g diet for parasitic hymenoptera; 9-day $LC_{50} > 1.8 \times 10^8$ cfu/g diet for a predaceous coleopteran; and 5-day $LC_{50} > 7.0 \times 10^7$ cfu/g diet for honeybees (MRID 41842708, 41842709, 41842710, and 41842711).

While certain subspecies of *Bt* have shown adverse effects on honey bees, minimal toxicity was shown in previously submitted tests with *Bti* on honey bees, according to the 1998 RED. Additionally, under Guideline 885.4380, *B. thuringiensis* subsp. *israelensis* was shown to have a 5-day $LC_{50} > 7.0 \times 10^7$ cfu/g diet for honey bees (MRID 41842711).

Based on the data and other information submitted and cited, adverse effects to honey bees and other nontarget insects are not anticipated as a result of exposure to *Bti* SUM-6218.

CONCLUSIONS FOR NONTARGET ORGANISMS

Based on the expected lack of exposure to the proposed manufacturing use product, and also the data discussed above, EPA concludes that risks to nontarget organisms as a result of the proposed registration of *Bti* SUM-6218 are not anticipated.

D. Threatened and Endangered Species Assessment

Since EPA has determined that no effects are anticipated for nontarget species exposed to *Bti* SUM-6218 as a result of the proposed labeled use, effects to federally listed threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to federally listed threatened and endangered species and their designated critical habitats for the proposed use of *Bti* SUM-6218, as labeled.

EPA Reviewer:
Shannon Borges, Lead Biologist, OPP/BPPD/MPB

Date: 4/17/13

DATA EVALUATION RECORD

REQUIREMENT (OCSPP Guideline No.): Avian Oral Toxicity (885.4050), Avian Inhalation Toxicity/Pathogenicity (885.4100), Wild Mammal Toxicity/Pathogenicity (885.4150), Freshwater Fish Toxicity/Pathogenicity (885.4200), Estuarine/Marine Fish and Invertebrate Testing (885.4280), Nontarget Plant Testing (885.4300), Nontarget Insect Testing (885.4340), Honey Bee Testing (885.4380), Endangered Species Assessment (non-guideline, not a data requirement)

ACTIVE INGREDIENT: *Bacillus thuringiensis* ssp. *israelensis* strain SUM-6218, synonym: *Bti* SUM-6218

CITATION: Full study citations provided under "Study Citations" below. MRIDs 486826-20 through -23, 486826-25 through -29.

SPONSOR: Summit Chemical Company, 235 South Kresson Street, Baltimore, MD 21224-2616

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided in each study report. The study reports contain summaries of scientific rationale, and, therefore, GLP as described in 40 CFR § 160 are not applicable. This DER does not contain FIFRA CBI.

SUMMARY: Scientific rationales were presented to fulfill the nontarget data requirements listed above for *Bacillus thuringiensis* ssp. *israelensis* strain SUM-6218. Rationales also included citations to studies developed on other *Bti* strains. A summary of each rationale is provided below.

CLASSIFICATION: All rationales cited below were determined to be **ACCEPTABLE**, with the exception of the Endangered Species Assessment. Endangered Species Assessments are not data requirements, so this study is classified as **SUPPLEMENTAL**.

RATIONALE SUMMARIES:

One or both of the following points was included in each of the rationales discussed below:

1) The combination of inert ingredients is not likely to pose any significant nontarget risks because the inert ingredients consist of byproducts of the fermentation process, including *Bacillus thuringiensis israelensis* spores, cell fragments, and spent media from soybean flour and minor undigested residues of starches, sugars, fats, proteins, and minerals.
2) EPA conclusions regarding nontarget organism risks to *Bacillus thuringiensis* as presented in the 1998 Reregistration Eligibility Decision (RED, see page 16) for *Bt* active ingredients and products registered at that time. EPA concluded that risks to nontarget organisms exposed to *Bacillus thuringiensis* are unlikely as long as the presence of heat labile exotoxins or beta-exotoxins is minimized.

Reviewer's Comments: The product pending for registration is a manufacturing use product that is 100% a.i., so there are no inert ingredients; however, point 1) is reasonable. For point 2), EPA notes that the conclusions presented in the RED were made specifically for the reregistration of products and use patterns registered at the time it was written. Since the pending registration is for a manufacturing-use product only, end-use product use patterns are not defined. The applicant submitted sufficient data to show that *Bti* SUM-6218 is identical to the bacterium originally isolated by Goldberg and Margalith in Israel in 1977[1], which is the active ingredient in other registered *Bti* based pesticides. Therefore, the conclusions in the 1998 RED would reasonably apply to this strain.

Avian Oral Toxicity (MRID 48682620); Avian Inhalation Toxicity (MRID 48682621)
In addition to points 1) and 2) discussed above, rationale was based on the following:

- Conclusions in the RED on chronic risks to birds (page 18) are quoted. EPA determined that chronic risks to birds were not triggered and additional data were not required. Additionally, results of previously submitted studies show that *Bti* was practically nontoxic to birds at 3.1 g/kg/day and 5 ml/kg/day to Northern bobwhite (*Colinus virginianus*) and mallard (*Anas platyrhynchos*) in avian oral studies (MRIDs 41842702, 41439006, and 41842703).
- Studies with *Bt* on mammals were also cited to support a conclusion that adverse effects are not expected in birds.

Reviewer's Conclusions: As noted above, data are available that sufficiently support bridging to data developed on the original *Bti* isolated and registered with EPA. The applicant also has submitted an acceptable bridging study (a 21-day *Daphnia* study, MRID 48682624) which sufficiently shows that *Bti* SUM-6218 does not produce heat labile exotoxins. This study is specified as a requirement in the 1998 RED to show that *Bacillus thuringiensis* based pesticides will not cause adverse effects in nontarget organisms, in addition to quality controls that ensure that beta-exotoxins are not produced. It should be noted, however, that EPA does not support citation of mammalian toxicity/pathogenicity data to fulfill avian data requirements, and these citations were not considered. Based on the available information, adverse effects to birds are not expected from exposure to *Bti* SUM-6218. The submitted rationale is **ACCEPTABLE**.

Wild Mammal Toxicity/Pathogenicity (MRID 48682622)
In addition to points 1) and 2) discussed above, rationale was based on the following:

- EPA conclusions from page 11 of the 1998 RED, which stated that to date, no known mammalian health effects have been demonstrated in any infectivity/pathogenicity study with *Bacillus thuringiensis*, and that mammalian toxicity/pathogenicity data will be waived in the future for the use patterns of registered products as long as product identity and manufacturing process testing data indicate that there is no mammalian toxicity associated with the strain.
- Citation of mammalian toxicity/pathogenicity data submitted previously to support registrations of *Bti*, including Accession Nos./MRIDs 142733, 41046704, 42006502, 43186101, 40951102, 96520, 96527, 96533, 109492, and 246968.

Reviewer's Conclusions: EPA notes that the conclusions from page 11 regarding waivers for additional testing refer to the use patterns of products registered at the time of the 1998 RED. However, as

[1] See memoranda from I. Barsoum to D. Greenway dated July 10, 2012 (with accompanying Data Evaluation Record) and November, 13, 2012.

discussed above, the applicant has provided sufficient data to support bridging to the cited studies. Additionally, the applicant submitted an Acute Injection Toxicity/Pathogenicity study and additional rationale to satisfy toxicology data requirements to support the human health risk assessment (see footnote 1 for references), and EPA has no reason to believe that studies with laboratory animals would not be representative of potential effects on wild mammals. Therefore, based on the rationale, studies cited, and study provided, adverse effects to wild mammals are not expected as a result of exposure to *Bti* SUM-6218. The submitted rationale is **ACCEPTABLE**.

Freshwater Fish Toxicity/Pathogenicity (MRID 48682623); Marine/Estuarine Fish and Invertebrate Testing (MRID 48682625)

Rationale was based on points 1) and 2) above in addition to the following:

- For freshwater fish: Under Guideline Number 885.4200, Freshwater Fish Toxicity, *Bti* was found to have an aqueous $LC_{50} > 8.7 \times 10^9$ cfu/L; oral $LC_{50} > 1.7 \times 10^{10}$ cfu/g food and an aqueous $LC_{50} > 1.4 \times 10^{10}$ cfu/L; oral $LC_{50} > 5.3 \times 10^9$ cfu/g food in rainbow trout and an aqueous $LC_{50} > 8.9 \times 10^9$ cfu/L; oral $LC_{50} > 1.3 \times 10^{10}$ cfu/g food and aqueous $LC_{50} > 1.6 \times 10^{10}$ cfu/L; oral $LC_{50} > 4.3 \times 10^9$ cfu/g food in bluegill sunfish (MRIDs 41439008, 41980105, 41439007, 41842704).
- For marine/estuarine fish and invertebrates: Under Guideline Number 885.4280 Estuarine and Marine Fish and Invertebrate Testing, *B. thuringiensis* subsp. *israelensis* was found to have a NOEL $> 2.0 \times 10^{10}$ cfu/g, NOEL $> 4.2 \times 10^9$ cfu/g food for grass shrimp; a NOEL$> 2.0 \times 10^{10}$ cfu/g food, oral LC $> 2 \times 10^{10}$ cfu/g food, $LC_{50} > 7.2 \times 10^9$ for sheepshead minnow; and a NOEL = 50 mg/kg sediment with a marine copepod (MRIDs 41540402, 41842706, 41540401, 41842707, and 41439010).

Reviewer's Conclusions: The applicant has provided sufficient information to allow for bridging to the cited data. The studies cited were determined to be acceptable. The rationales submitted to fulfill these data requirements are **ACCEPTABLE**.

Nontarget Plant Testing (MRID 48682626)

Rationale was based on point 1) discussed above and the following:

- EPA conclusions from the 1998 RED stating that testing on nontarget plants was waived because a literature search indicated no detrimental effects to plants.
- EPA requires nontarget plant testing only when the active ingredient is taxonomically related to known plant pathogens. *Bti* is not a plant pathogen and is not related to known plant pathogens.

Reviewer's Conclusions: This rationale is **ACCEPTABLE**.

Nontarget Insect Testing (MRID 48682627) and Honey Bee Testing (MRID 48682628)

Rationale was based on point 1) discussed above and the following:

- EPA conclusions from the 1998 RED (pages 20 and 21) about risks to nontarget insects and honey bees, stating that adverse effects to several orders of nontarget insects were not observed in tests submitted to support products that were registered at the time. Additionally, the RED states that additional testing on nontarget insects (but not honey bees) was waived because *Bt* functions by a toxic mode of action and does not cause epizootics in the field.
- Under Guideline Number 885.4340 Nontarget Insect Testing, *B. thuringiensis* ssp. *israelensis* was found to have a 16-day $LC_{50} > 1.5 \times 10$ and 16-day NOEL $= 2.5 \times 10^4$ cfu/g for the green lacewing; 30-day $LC_{50} > 7.9 \times 10^7$ cfu/g diet for parasitic hymenoptera; 9-day $LC_{50} > 1.8 \times 10^8$

cfu/g diet for a predaceous coleopteran; and 5-day $LC_{50} > 7.0 \times 10^7$ cfu/g diet for honeybees (MRID 41842708, 41842709, 41842710, and 41842711).

- Minimal toxicity was shown in tests with *Bti* on honey bees, according to the 1998 RED.
- Under Guideline Number 885.4380, Honey Bee Testing, *B. thuringiensis* ssp. *israelensis* was shown to have a 5-day $LC_{50} > 7.0 \times 10^7$ cfu/g diet for honey bees (MRID 41842711).

Reviewer's Conclusions: As noted above, sufficient data have been submitted to allow for bridging to the cited data and to conclude that effects on nontarget insects and honey bees are not expected as a result of exposure to *Bti* SUM-6218. The rationales are **ACCEPTABLE**.

Endangered Species (Non-guideline)
Rationale was submitted to support a conclusion that threatened and endangered species as listed by the U.S. Fish and Wildlife Service and National Marine Fisheries Service will not be affected as a result of the proposed registration of *Bti* SUM-6218.

Reviewer's Conclusions: An assessment of the effects to listed species will be included in the ecological risk assessment for *Bti* SUM-6218. The rationale is **SUPPLEMENTAL**.

STUDY CITATIONS

Rose, R.I. 2011. Avian Oral Toxicity for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682620.

Rose, R.I. 2011. Avian Inhalation Toxicity/Pathogenicity for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682621.

Rose, R.I. 2011. Wild Mammal Toxicity/Pathogenicity for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682622.

Rose, R.I. 2011. Freshwater Fish Toxicity/Pathogenicity for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682623.

Rose, R.I. 2011. Estuarine and Marine Fish and Invertebrate Testing for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682625.

Rose, R.I. 2011. Nontarget Plant Testing for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682626.

Rose, R.I. 2011. Nontarget Insect Testing for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682627.

Rose, R.I. 2011. Honeybee Testing for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682628.

Rose, R.I. 2011. Threatened and Endangered Species Analysis for Summit's *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) MP. Completed July 28, 2011. MRID 48682629.